

K072730

## 510(k) SUMMARY

MAR 27 2008

DENTSPLY International  
Susquehanna Commerce Center West  
221 West Philadelphia Street, Suite 60  
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED:

TRADE OR PROPRIETARY NAME: CERCON® ABUTMENTS:  
FRIADENT® CERCON® Abutment  
ANKYLOS® CERCON® Balance Abutment

CLASSIFICATION NAME: Endosseous dental implant abutment 872.3630

PREDICATE DEVICES: FRIALIT®-2 CeraBase Abutment K980630/K994376  
ANKYLOS® Balance Abutment K012681/K041509

DEVICE DESCRIPTION: The CERCON® ABUTMENTS are part of the FRIADENT® prosthetics.

The CERCON® ABUTMENTS are available as straight and angled abutments with different gingival margins and in multiple diameters and shades.

INTENDED USE: The FRIADENT® CERCON® Abutment is indicated for the support of exceptionally esthetic, single crowns in the anterior region of the maxilla or mandible region. Also ideal for XiVE®, FRIALIT® or FRIALIT®-2 cases involving very thin soft tissue.

The ANKYLOS® CERCON® Abutment is indicated for the support of highly esthetic single tooth crowns in the anterior region of the maxilla and mandible, including where the mucosa is very thin, in combination with implants of the ANKYLOS® implant system.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the CERCON® ABUTMENTS have been used in legally marketed devices or were found safe for dental use. They are made of zirconia ceramic in accordance with industry standards. In addition, the manufacturing methods are identical to legally marketed devices. Therefore, it was determined that no additional biocompatibility testing was necessary.

We believe that the prior use of the components of the CERCON® ABUTMENTS in legally marketed devices, the performance data provided, and the biocompatibility history support the safety and effectiveness of the CERCON® ABUTMENTS for the indicated uses.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 27 2008**

Ms. Helen Lewis  
Director of Corporate Compliance and Regulatory Affairs  
DENTSPLY International, Incorporated  
Susquehanna Commerce Center West  
221 West Philadelphia Street, Suite 60  
York, Pennsylvania 17405-0872

Re: K072730  
Trade/Device Name: Cercon® Abutments  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutments  
Regulatory Class: II  
Product Code: NHA  
Dated: February 12, 2008  
Received: February 13, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072730

Device Name: CERCON® ABUTMENTS

### Indications for Use:

The FRIADENT® CERCON® Abutment is indicated for the support of exceptionally esthetic, single crowns in the anterior region of the maxilla or mandible region. Also ideal for XiVE®, FRIALIT® or FRIALIT®-2 cases involving very thin soft tissue.

The ANKYLOS® CERCON® Abutment is indicated for the support of highly esthetic single tooth crowns in the anterior region of the maxilla and mandible, including where the mucosa is very thin, in combination with implants of the ANKYLOS® implant system.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karin Mahney for MCR  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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